

SUMMARY OF SAFETY AND EFFECTIVENESS
Orthofix Inc.
Guided Growth System Quad-Plate

Summary Preparation

Date: June 10, 2010

JUN 10 2010

510(k)-Submitter: Mary E. Biggers, RAC
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Device Trade Name: Guided Growth System™

Device Common
Name: bone plate

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.

Classification Name: plate, bone, growth control, pediatric, epiphysiodesis
(21 CFR Parts 888.3030)

Product Code: OBT

Indications for Use: The Guided Growth System plates are designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Predicate Device: The Orthofix Inc. Guided Growth System Quad-Plate is substantially equivalent in design, function, and intended use to the Orthofix Guided Growth System eight-Plate®. The Orthofix Guided Growth System eight-Plate, manufactured by Orthofix Inc. of McKinney, Texas, was originally cleared by FDA under K031493 on November 20, 2003.

Device Description: The Guided Growth System is designed for the gradual correction of pediatric deformities in both the upper and lower extremities. The device can be used for correction of congenital deformities as well as correction of acquired deformities, provided that the physis (growth plates) are not fused. The plates feature a contoured waist and low profile for pediatric usage. There is a center hole in the plate for a temporary guide pin to be implanted to ensure accurate application of the plate. The plates are attached to the external surface of the bone over the growth plate by two or four screws. These screws are not locked to the plate, but rather are allowed to swivel and diverge in their position as bone growth occurs. The implant acts like a flexible hinge, permitting growth at the growth plate to gradually straighten the limb. Immediately after implantation, the patient is allowed mobility and weight bearing.

Biomechanical Testing:

In order to demonstrate that the Guided Growth System Quad-Plate has the mechanical properties necessary to perform its intended use, and that the Quad Plate performs as well as or better than the predicate device, Orthofix has conducted mechanical and functional testing of the Quad-Plate in accordance with ASTM F564-02 Standard Specification and Test Method for Metallic Bone Staples. The testing was successfully completed demonstrating the Quad Plate performs as well as the Guided Growth System eight-Plate.

Material: The Guided Growth System eight-Plate, Quad Plate and screws are made from titanium alloy, Ti6AL-4V ELI conforming to ASTM F136.

Sterilization: The Guided Growth eight-Plate, Quad-Plate and Bone Screws are supplied NON-STERILE and require sterilization prior to use.

Substantial Equivalence: The Guided Growth System Quad Plate is substantially equivalent in design and function to the Guided Growth System eight-Plate. The Guided Growth System eight-Plate received 510(k) clearance under K031493 on 11-20-03.

Features	eight-Plate®	Quad-Plate
Indications for Use	<i>"The Guided Growth Plate is designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius)"</i>	Identical
Material	Ti6A14V ELI	Identical
Features	eight-Plate®	Quad-Plate
Fixation Method	Bone Screws	Identical
Number of Fixation Points	Two	Four
Design Features	a contoured waist and low profile for pediatric usage	Identical
Size Ranges (lengths)	12mm and 16 mm	16 mm and 22mm

Conclusion: Based upon the results of biomechanical testing the Guided Growth System Quad-Plate has the mechanical properties to perform its indications for use and is considered to be substantially equivalent to the predicate device in design, material and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Orthofix, Inc.
% Ms. Mary Biggers
1720 Bray Central Drive
McKinney, Texas 75069

JUN 10 2010

Re: K093442

Trade/Device Name: Guided Growth System Quad-Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: OBT
Dated: May 10, 2010
Received: May 12, 2010

Dear Ms. Biggers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

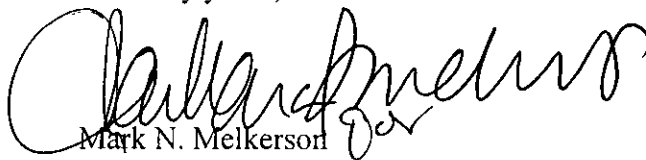
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M".

Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Page ____ of ____

510(k) Number (if known):

K093442

Device Name:

**"Guided Growth System Quad-Plate"
(bone plate)**

Indications for Use:

The Guided Growth Plates are designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius)

Prescription Use: X
(Per 21 CFR 801.109)

Or

Over-The-Counter ____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093442